

NYRx Notice to Providers: Biologic Drugs Originator vs Biosimilar

May 20, 2026

Types of Drugs

Originator or Reference Biologic

An originator or reference biologic is the first version of a product approved by the FDA. The originator serves as a benchmark for other manufacturers who want to bring a similar biologic to market.

Biosimilar

A biosimilar is a biologic drug that is highly similar to the originator or reference product. To be FDA-approved, the biosimilar must show no meaningful clinical difference in safety, purity, or effectiveness compared to the originator. Biosimilars are generally less expensive than their originator.

Both originator and biosimilar:

- Are derived from living sources
- Provide the same clinical benefits
- Are administered at the same strength and dosage
- Are not expected to result in new or increased side effects

Interchangeable Biosimilar

An interchangeable biosimilar is a biosimilar that may be substituted for its reference biologic at the pharmacy, in accordance with state law.

New York State Education Law Title 8, Article 137, section 6816-A, permits a pharmacist to substitute an FDA-designated interchangeable biosimilar for a prescribed reference biologic. The law requires the pharmacist to notify both the prescriber and the patient of the product dispensed and allows prescribers to prohibit substitution when deemed clinically necessary.

What Providers Need to Know

Certain biologic drugs are subject to prior authorization requirements under the NYRx Pharmacy Program. The NYRx Preferred Drug Program (PDP) promotes the use of less expensive, equally effective drugs when medically appropriate through the [Preferred Drug List \(PDL\)](#). When clinically appropriate,

use of preferred agents is associated with comparable clinical outcomes and a significantly lower total cost of care. Non-preferred agents are often two to ten times more costly than preferred alternatives.

Biologic drugs are included in the following PDL drug classes:

Immunomodulators - Systemic

Drugs in the [Immunomodulators – Systemic](#) drug class are included on the [NYRx Preferred Drug List \(PDL\)](#) and are subject to prior authorization (PA) requirements of the NYRx Preferred Drug and Drug Utilization Review Programs.

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic ^{CC, ST}		
Interleukin Inhibitors		CLINICAL CRITERIA (CC) <ul style="list-style-type: none"> Confirm diagnosis of FDA-approved or compendia-supported indication and Medicaid covered indication STEP THERAPY (ST) For indications not specified below <ul style="list-style-type: none"> Trial of a non-specific anti-inflammatory drug such as an aminosalicylate or immunosuppressant, or a non-biologic disease-modifying anti-rheumatic drug (DMARD) Trial of a TNF inhibitor prior to treatment with a JAK inhibitor INDICATION-SPECIFIC REQUIREMENTS: <ul style="list-style-type: none"> Asthma: <ul style="list-style-type: none"> history and concurrent use of a corticosteroid Nasal polyps: <ul style="list-style-type: none"> history and concurrent use of an intranasal corticosteroid Atopic dermatitis: <ul style="list-style-type: none"> Trial with a topical prescription product for a duration of at least 3 months. For JAK inhibitors: Trial of topical prescription product and systemic product for a combined duration of at least 6 months. COPD: <ul style="list-style-type: none"> History and concurrent use of a long acting beta agonist (LABA) + long acting muscarinic agonist (LAMA) + inhaled corticosteroid (ICS)
Cosentyx® Dupixent® Ebglyss™ 1 Fasenna® Nucala®	Actemra® SQ Adbry™ Avtozma® Bimzelx® Illumya® Imuldosa® Kevzara® Kineret® Nemluvio® Omvoh™ SQ Otufi™ Pyzchiva® Selarsdi™ Skyrizi® Skyrizi® On-Body Spevigo® Starjemza™ Stelara® Steqeyma® Taltz® Tremfya® Tyenne® ustekinumab Yesintek™	

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
IX. Immunologic Agents		
Immunomodulators – Systemic CC, ST		
JAK Inhibitors		
	Cibinqo™ Olumiant® Rinvoq™ ER Rinvoq® LQ Xeljanz® Xeljanz® XR	
TNF Inhibitors		
adalimumab (Boehringer Ingelheim) [†] Enbrel® Humira®	Abridata™ adalimumab Amjevita™ Cyltezo® Cimzia® Hadlima™ Hulio® Hyrimoz® Idacio® Simlandi® Simponi® Yuflyma® Yusimry™ Zymfentra™	
Miscellaneous		
Xolair®	Entyvio® SQ Ocrencia® SQ Otezla® Otezla XR™ Rhapsido® Sotyktu™ Tezspire® pen Velsipity™	

Insulin – Long-Acting

Drugs in the [Insulin – Long-Acting](#) drug class are included on the NYRx PDL and are subject to PA requirements of the NYRx Preferred Drug Program.

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VI. Endocrine and Metabolic Agents		
Insulin – Long-Acting		
insulin glargine-YFGN Lantus® Solostar®, vial	Basaglar® Basaglar® Tempo™ insulin degludec vial, pen (gen Tresiba) insulin glargine max solostar (gen Toujeo® Max Solostar®) insulin glargine solostar (gen Toujeo® Solostar®) Rezvoglar™ Semglee®-YFGN: vial, pen Toujeo® Solostar® Toujeo® Max Solostar® Tresiba®	

Insulin – Rapid-Acting

Drugs in the Insulin – Rapid-Acting drug class are included on the NYRx PDL and are subject to PA requirements of the NYRx Preferred Drug Program.

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VI. Endocrine and Metabolic Agents		
Insulin – Rapid-Acting		
insulin aspart (gen Novolog®) cartridge, vial, pen insulin lispro (gen Humalog® U100) vial, pen insulin lispro junior (gen Humalog® Jr.)	Admelog® Afrezza® Apidra® Fiasp® Penfill, FlexTouch, Pumpcart, vial Humalog® Jr. 100 U/mL Kwikpen Humalog® 100 U/mL vial, pen, cartridge, Tempo™ Humalog® 200 U/mL Kirsty™ Lyumjev® Lyumjev® Tempo™ Merilog™ Solostar, vial Novolog® cartridge, vial, FlexPen	

Colony Stimulating Factors

Drugs in the Colony Stimulating Factors drug class are included on the NYRx PDL and are subject to PA requirements of the NYRx Preferred Drug Program.

Preferred Drugs	Non-Preferred Drugs	Coverage Parameters
VIII. Hematological Agents		
Colony Stimulating Factors		
Fulphila® Neupogen®	Fylnetra® Granix® Leukine® Neulasta® Nivestym™ Nypozi® Nyvepria™ Releuko™ Rolvedon® Stimufend® Udenyca® Zarxio® Ziextenzo®	

Preferred drugs will not require PA if the required coverage parameters are found in the member’s Medicaid claim history and clinical criteria are met at the time of pharmacy claim submission. Non-preferred drugs in these classes require PA, unless indicated otherwise.

Resources

- [9 Things to Know About Biosimilars and Interchangeable Biosimilars | FDA](#)
- [Biosimilar Product Information | FDA](#)
- [FDA Overview for Health Care Professionals](#)

- [NYRx Education & Outreach Website](#)
- [NYRx Preferred Drug List](#)
- [NYRx Preferred Drug Quick List](#)
- [NYRx Prior Authorization Submission Guide](#)

Contact Information

The NYRx Education & Outreach Call Center is available by phone at 1-833-967-7310 or by email at NYRxEO@primetherapeutics.com from 8:00 AM to 5:00 PM ET, Monday through Friday, excluding holidays.

The NYRx Education & Outreach team hosts virtual office hours every week for stakeholders to ask questions related to NYRx and care coordination. Visit the [NYRx Education & Outreach website](#) for more information.